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PATENT
CUSTOMER 22,852
Attorney Docket No. 01142.0102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Mark H. PAUSCH *et al.*) Group Art Unit: 1646
)
Serial No.: 09/786,033) Examiner: M. Brannock
)
Filed: July 3, 2001)
)
For: METHODS OF IMPROVING THE)
FUNCTION OF HETEROLOGOUS)
G PROTEIN-COUPLED)
RECEPTORS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In reply to the Office action mailed July 1, 2003, Applicants submit the following response, with a concurrently-filed petition for a three-month extension of time and appropriate fee. Thus, this Response is due by Monday, November 3, 2003, and is timely filed.

In this Office action the Office imposed a third restriction requirement in this application. The Office now asserts that claims 1-29 are directed to three groups of inventions that are not so linked as to form a single inventive concept under PCT Rule 13.1. Office action, page 2. The three groups are:

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Group I, claims 1-14, 20-24, 28, and 29, "relat[ing] to a deletion in the third intracellular domain, drawn to a yeast cell comprising a heterologous GPCR modified with a deletion in the third intracellular domain";

Group II, claims 1-3, 9-12, and 15-20, "relat[ing] to a substitution modification in the third intracellular domain, drawn to a yeast cell comprising a heterologous GPCR modified with a substitution in the third intracellular domain"; and

Group III, claims 21-23, and 25-28, "relat[ing] to a deletion of the carboxyl terminal domain, drawn to a yeast cell comprising a heterologous GPCR modified with a deletion in the carboxyl terminal domain." *Id.*

Applicants elect to prosecute Group I, claims 1-14, 20-24, 28, and 29, with traverse.

Under PCT Rule 13.1, an international application may relate to "a group of inventions so linked as to form a single inventive concept." And under Rule 13.2, the unity of invention requirement is met with respect to a group of inventions when there is a "technical relationship" involving one or more of the same or corresponding "special technical features"—meaning those features that distinguish the claimed inventions over the prior art. Applicants submit that claims 1-29 are so linked as to form a single inventive concept and, therefore, the requirements of these rules have been met.

In support of its conclusion that claims 1-29 lack unity of invention, the Office cites U.S. Patent No. 5,576,210 to Sledziewski *et al.* ("Sledziewski") as disclosing a yeast cell comprising a nucleic acid sequence encoding a modified heterologous G-protein coupled receptor, wherein the modification comprises a mutation in an intracellular domain. Office action, page 3. Further, the Office suggests that this

mutation results in improved functional response in a cell-based assay, and that the modified receptor is a muscarinic acetylcholine receptor. *Id.* Based on this alleged teaching, the Office concludes that the invention set forth in Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, but rather, it simply defines an improvement over the prior art.

Applicants disagree with the Office's reading of Sledziewski. Sledziewski discloses yeast cells containing DNA sequences encoding hybrid G-protein coupled receptors that, when expressed, enable the host cells to bind and respond to G-protein coupled receptor ligands that would not otherwise elicit a yeast mating response. See Sledziewski, col. 7, ll. 60-65. Furthermore, Sledziewski discloses replacement of the DNA sequence encoding at least one domain other than the ligand-binding domain of a mammalian receptor with the DNA sequence encoding the corresponding domain of a yeast G-protein coupled receptor. See, for example, *id.*, col. 8, ll. 5-10; col. 3, ll. 4-26. In contrast, the present invention is drawn to yeast cells comprising heterologous G-protein coupled receptors with modifications in the third intracellular loop of the effector domain and/or the carboxy-terminal internal effector domain. But the claimed modifications are to wild-type receptor sequences, they are not replacement of portions of the native receptor sequences with the corresponding domain of a yeast G-protein coupled receptor. *Cf.* Sledziewski, col. 8, ll. 5-10. Thus, the claimed invention is patentably distinct from Sledziewski and the Office's reasoning pertaining to lack of unity of invention under PCT Rule 13.1 is not persuasive. For these reasons, Applicants request that the Office reconsider and withdraw the restriction requirement, and examine claims 1-29 on the merits in this application.

In addition to the restriction of the claims into groups I-III, the Office contends the claims are directed to more than one species of the generic invention and that "[t]hese species are deemed to lack unity of invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1." Office action, page 4. The different species are different receptor types. *Id.* Applicants are required to: (1) "elect a single species to which the claims shall be restricted if no generic claim is finally held allowable"; and (2) "identify the claims readable on the elected species." *Id.* The Office's reasoning in imposing the species election requirement is set forth in the Office action at page 5.

In response, Applicants elect muscarinic acetylcholine receptors, with traverse. Claims 1-7, 9, 13, 15-25, 28, and 29 are readable on the elected species.

Applicants traverse because the invention does not depend on the individual receptor types recited in the claims. That is, the invention is not based on the receptor type used in the claimed methods. The Office's requirement that a single receptor type be elected is improper as the receptor is not relevant to the issue of whether there is unity of invention. Accordingly, the Office should also withdraw this requirement.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the restriction requirement. In the event that the Office does not withdraw the restriction requirement, Applicants reserve the right to Petition the Commissioner to have the restriction requirement reviewed and/or to prosecute the non-elected claims in divisional or continuation applications.


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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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